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Report of the 2012 Capacity Building for HIV-HPV Clinical Trials Recruitment among Minority Underserved Populations of Hispanic Origin in Puerto Rico

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Despite the high burden of both cancer and HIV among minority populations in the United States (US) and Puerto Rico (PR) (1), their participation in related clinical trials (CT) is low (2-4). CT are the basis for the development of new preventive and therapeutic interventions, thus, under-representation of population sub-groups in CT may lead to health disparities (5).

On May 25, 2012 the educational intervention entitled Capacity Building for HIV-HPV Clinical Trials Recruitment among Minority Underserved Populations of Hispanic Origin was held in PR. This effort aims to establish a comprehensive long-term relationship to target and eradicate cancer health disparities and improve HIV/cancer alliances between academia and the community. The specific aims of the workshop were: 1) explore venues to increase physician participation in CT and enhance communication between healthcare providers and patients in relation to CT, 2) present study findings from our research partners from the AIDS Malignancy Clinical Trials Consortium (AMC) (6) with the objective of increasing awareness and willingness among health care professionals in PR to participate in future HIV/HPV-related CT, 3) encourage health care providers to suggest CT for patients newly diagnosed with cancer, 4) encourage physicians to inform and educate HIV+ patients about the availability and benefits of CT and to offer participation in CT as a choice, and 5) understand the knowledge and willingness among health care professionals to be part of CT. This workshop consisted of seven oral presentations. Pre- and post-test evaluations were used to assess the impact of the activity in participants' knowledge. Also, a survey was administered, with the aim of creating a profile of the health care professionals as well as measures to understanding their knowledge and attitudes towards CT. Forty-two persons participated in this activity (Table 1) and 4 graduate students from the School of Public Health, Medical Sciences Campus participated as volunteers.

Scientific highlights

We summarize the workshop topics discussed by the speakers, which included a description of the burden of HIV/AIDS and cancer in PR, presentation of ongoing projects, and a discussion of future plans for the promotion of HIV/HPV CT capacity building and research in PR.

The Burden of HIV in PR

Gladys Girona-Lozada, MSc, is an epidemiologist at the PR HIV/AIDS surveillance system. Her presentation described the burden of HIV/AIDS in PR, using data from this surveillance system and data collected through the PR Medical Monitoring Project (MMP) 2009-2010 cycle. The MMP is a supplemental surveillance system that monitors clinical outcomes and behaviors of persons living with HIV/AIDS (PLHA) receiving medical care. Main findings discussed included that in 2010, PR was one of the top ten US states/territories in terms of the number of cumulative AIDS cases (33,597 reported through 2010), AIDS incidence rate (14.9 per 100,000) and prevalence (329.1 per 100,000) (7). From 1981-2012, the largest percentage of all HIV diagnoses in PR were in males (73.9%) and in persons aged 25-34 years (35.6%); 80% of HIV cases developed AIDS. The low participation of this population in CT was documented (6% had participated in a CT within the past 12 months).

Epidemiological profile of HPV-related cancers among HIV infected people in PR

Ana Patricia Ortiz, PhD, MPH, is an epidemiologist and one of the principal investigators of this initiative. Her talk described the high burden of HPV infection and HPV-related cancers among PLHA (8). In addition, she described the incidence and survival of HPV-related cancers among HIV-infected persons in PR. She also documented that HIV-infected persons have a higher burden of HPV-related cancers than the general population of PR, and that the risk of death among HIV-infected persons who develop cancer is higher than among those that do not develop a malignancy (9). The need to augment epidemiological data regarding the burden of HPV and related malignancies among Hispanic PLHA was highlighted.

Multilevel Capacity Building for HIV-HPV CT Recruitment among Minority Underserved Populations of Hispanic Origin

Vivian Colón-López, PhD, MPH, is an epidemiologist and one of the principal investigators of this initiative. Her presentation provided an overview of the current study, she discussed additional ongoing projects, preliminary data, and action plans for future cancer research among PLHA. Among key points, she documented the increasing incidence of anal cancer among men in PR (10) and the higher incidence and mortality rates of penile cancer in PR men as compared with other racial/ethnic groups (1). Given the high burden of HPV infection, the need to educate PLHA and health care providers in PR about cancer and available screening options was highlighted. Also, the need for a multilevel intervention to increase participation of both health care professionals and PLHA in CT was discussed.

The AIDS Malignancy Clinical Trials Consortium

María T. Botello-Harbaum, MS, EdD, is the Outreach Manager for the AMC Operations and Data Management Center. The main objective of the AMC is to investigate new treatments and prevent malignancies in PLHA in the US and internationally. The current AMC disease areas are: Kaposi's sarcoma, Lymphoma, HPV-related diseases, Non-AIDS-defining cancers and International HIV malignancies (6). The talk of Dr. Botello aimed to: 1) increase the understanding of the role of the AMC in building capacity for future HIV-HPV trials, 2) increase the knowledge of the mission and CT conducted by the AMC, and 3) identify the recruitment and retention initiatives implemented to increase enrollment in AMC trials. Some of these initiatives include patient navigation (which helps ensure that patients receive culturally competent care), capacity building for health professionals and community outreach. No AMC site currently exists in PR.

The HPV Working Group

Joel Palefsky, MD is Professor of Medicine at the University of California, San Francisco (UCSF), the Chair of the AMC HPV Working Group, the head of the AMC HPV Virology Core Lab and one of the collaborators of this initiative. Dr. Palefsky's talk described the HPV working group goals, sites and studies; studies include epidemiological, novel therapies and vaccine studies. The target diseases of the HPV working group are: anal and cervical cancer and their precursors, and oral HPV infection (11). His talk underscored the need of trained clinicians in high-resolution anoscopy (HRA) and of expanding expertise and availability of this procedure. He also highlighted the need for the development and evaluation of new methods of prevention and treatment of anal and cervical cancers and their cancer precursors in HIV-infected patients. Furthermore, the need for evaluating anal neoplasia screening as a standard of care for the prevention of anal cancer in certain populations was also discussed.

IMPACT: Investigating Motivations for Participation in Anal Cancer Trials

Nicolas Sheon, PhD is a medical anthropologist at the Center for AIDS Prevention Studies at UCSF. Dr. Sheon's presentation described the motivations expressed by HIV-infected persons for joining a randomized CT that assessed the efficacy of screening for and treatment of anal cancer precursor lesions to reduce the incidence of anal cancer, and highlighted some of the gender and ethnic differences in attitudes about the trial. He evidenced that different ethnic groups may be more or less willing to disclose information related to their diagnosis (anal neoplasia) because of the implications that this may have in their culture, as this diagnosis may be associated with anal sexual practices. He also highlighted the fact that HIV-infected individuals preferred to participate in an arm of a cancer CT in which pre-cancerous lesions would be removed compared with close

observation, but that most were willing to be randomized and remain in the trial regardless of their assigned trial arm (12).

Clinical Experience: Establishing an Anal Dysplasia Clinic in PR

Humberto M. Guiot, MD is an Infectious Diseases specialist and one of the clinical collaborators of this initiative. During the past year, he has received training in HRA and has established an anal dysplasia clinic in the Medical Sciences Campus of the UPR. His clinical experience in this process was described in this talk. Up to this point, Dr. Guiot's clinic has served mostly men (78%), PLHA (91%) and persons with Medicaid and government-based health insurance (81%). He serves a high-risk population, where a considerable number of patients with abnormal anal cytology or with high-risk HPV infection in the anus are found to have high-grade neoplasia during his clinical evaluations. He highlighted in his conference that in PR there is a need for trained anoscopists and for anal dysplasia clinics.

conclusion

This educational intervention was well received by our target audience; participants were highly satisfied with the workshop. The vast majority of participants (>95%) indicated that they "strongly agreed/agreed" that this conference was relevant, will be useful, fulfilled their expectations, and was one they would recommend to others. Results from the pre- and post-test evidenced an increase in knowledge. Our next steps include: 1) Future publications which will report on the results obtained from the interview administered to participants, regarding knowledge and attitudes towards CT and 2) Continued collaboration with the AMC, in order to promote the participation of PLHA in PR in cancer-related CT. Opportunities such as this one that create a strong foundation for capacity building will help to develop successful efforts in the future for recruitment in AMC and other CT in PR.

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Table 1

Profile of workshop participants (n=42)

Specialty	Total (%)
Physicians	12 (28.6)
Registered nurse	15 (35.7)
Study coordinator	4 (9.5)
Case manager	5 (11.9)
Social worker	1 (2.4)
Counselor	1 (2.4)
Administrative positions	4 (9.5)